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09/853,343	05/10/2001	Allan Bradley	11635-005001 OTA 00-43	8644

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EXAMINER
CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/853,343	Applicant(s) BRADLEY ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above claim(s) *58-81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-57,82 and 83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No.

DETAILED ACTION

1. The response to restriction requirement (Paper No. 10) filed on August 5, 2002 has been entered and considered.

2. The Information Disclosure Statement (Paper Nos. 7 and 8) filed on May 14, 2002 and August 5, 2002 has been entered and considered.

3. Applicant's election without traverse of Group I (claims 1-57, 82-83) in Paper No. 10 is acknowledged. Claims 58-81 are withdrawn from further consideration. Applicants' request for rejoinder of method claims once the product claims are allowable, is considered and found not persuasive because the claims drawn to the product claims are classified in separate class and subclass. As compared to method claims in Groups II and III. The method claims in Group II and III are further grouped into separate class subclass. Classification is prime basis for restriction which cant not be rebutted. Thus the restriction requirement is still deemed proper.

4. Claims 1-57, and 82-83 in Group I are considered for examination in this office action.

Double Patenting

5a. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Claims 1-3, 13, 18-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 18-20 of U.S. Patent No.6,048,695 ('695). Although the conflicting claims are not identical, they are not patentably distinct from each other because the biological molecule of the instant claims encompasses nucleic acids as claimed in the patented claims ('695). Biological molecule comprises a nucleic acid (DNA or RNA), a protein, or a peptide, lipid or a polysaccharide molecule. Further, the compound used to modify a nucleic acid of the patented claims has the said formula as claimed in the instant claims. The instant claims differ from patented claims only in reciting 'biological molecule' in place of 'nucleic acid' which is an obvious variation of the term nucleic acid. Further the high-density microarray disclosed in the patented claims is recited as article in the instant claims. Therefore, the instant claims are not patentably distinct and hence are rejected under obviousness-type double patenting.

5b. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefore ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-3, 8-11, 18-28, and 54 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 8-25, and 27-32 of prior U.S. Patent No. 09/546,085. This is a

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-10, 12, 32, 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are indefinite or unclear because of reciting an 'analog or mimetic thereof' and is not clear whether the mimetic thereof refers to analogs /mimetics of a biological molecule or to analogs/mimetics of a polysaccharide molecule. Amendment to properly recite the term 'thereof' would obviate this rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

by Krinski et al. (USPN 4,[illegible])

Krinski et al. teach a modified biological molecule (protein) wherein Krinski et al. teach that the modified biological molecule comprises a biological molecule covalently bound to a compound having formula R_1-X-R_2 and the compound could be glycodoxypropyltrimethoxy-silane (see column 3, lines 8-10, column 4, lines 31-41). Krinski et al. also teaches that the modified biological molecule could be a protein material, a peptide or a polypeptide (see column 4, lines 31-53); the alkoxysaline could be a propyl trimethoxy silane (see column 4, lines 31-41); and could include addition of amino groups to the modified biological molecule (see column 4, lines 54-67). Thus, the disclosure of Krinski et al. meets the limitations in the instant claims.

(b) Claims 1-3,12-13, 15, 23-28, are 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Plueddemann (USPN. 4,231,910).

Plueddemann teaches a modified biological molecules (primer compositions) on a solid support wherein Plueddemann discloses a solid support and immobilized modified biological molecules (see column 2, lines 21-39, column 3, lines 22-29). Plueddemann also teaches that (i) the solid support comprises glass, quartz, aluminum, titanium, and metal oxides (see column 3, lines 22-29); and (ii) solid support could also comprise polyesters, polycarbonates, polyethelene terephthalate, and nylon (column 3, lines 30-54). Thus the disclosure of Plueddemann meets the limitations in the instant claims.

(c) Claims 1-3,12-15, 23-28, 32-38, 47, and 82-83 are rejected under 35 U.S.C. 102(e) as being anticipated by Beattie (USPN. 6,426,183).

(oligonucleotides) immobilized to said solid support (see column 3, lines 1-4). Beattie also

disclose that (i) the solid support comprises silane containing substrates which include hydroxyl groups (see column 4, lines 46-54, column 3, lines 5-9); (ii) solid support comprises glass, quartz, metal oxides (see column 4, lines 13-36); and (iii) biological molecules on solid support are immobilized in discrete spots at a suitable distance from one another, typically from about 0.01 to 10mm of one another (see column 12, lines 25-31); (iv) nucleic acid comprises plurality of CpG island tags (see column 8, lines 10-28); and (v) method of making modified biological molecule and method of making a microarray comprising modified biological molecule (see 2, lines 12-67, and column3, lines 1-15). Thus the disclosure of Beattie meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Claims 16-17, 30-31,40-46, 48-57 rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie (USPN. 6,426,183) and in view of Pinkel et al. (USPN. 5,830,645).

Beattie teaches microarrays comprising modified biological molecules wherein Beattie discloses that the microarray comprises (i) a solid support and (ii) a modified biological molecule (oligonucleotides) immobilized to said solid support (see column 3, lines 1-4). Beattie also disclose that (i) the solid support comprises silane containing substrates which include hydroxyl groups (see column 4, lines 46-54, column 3, lines 5-9); (ii) solid support comprises glass, quartz, metal oxides (see column 4, lines 13-36); and (iii) biological molecules on solid support are immobilized in discrete spots at a suitable distance from one another, typically from about 0.01 to 10mm of one another (see column 12, lines 25-31); (iv) nucleic acid comprises plurality of CpG island tags (see column 8, lines 10-28); and (v) method of making modified biological molecule and method of making a microarray comprising modified biological molecule (see 2, lines 12-67, and column3, lines 1-15). However, Beattie did not disclose biological molecule comprising nucleic acid derived from human or mouse and a kit comprising biological molecule.

Pinkel et al. teaches a microarray based determination of relative copy number of target nucleic acid wherein Pinkel et al. teaches nucleic acids derived from any organism (see column 2, lines 50-54); comprises genomic DNA isolated form normal and abnormal or diseased tumor cells (see column 3, lines 15-41, column 6, lines 60-67); target nucleic acids could be derived from clones from genomic library, specific gene or from a chromosomal region (see column 3,

phage (see column 7, lines 22-27); an array comprises 300 genomic fragments clusters per spot

with a complexity of about 1 kb and about 1 megabase in size and with a factor of 10 copies of target nucleic acids (see column 4, lines 6-45and column 10, lines 24-34); a kit comprising solid supporthaving an array of nucleic acids bound thereto (see column 3, lines 43-50).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify an array of DNA as taught by Beattie with an array comprising varied DNA fragments as taught by Pinkel et al. to achieve expected advantage of developing an array comprising genomic clones because Beattie states that arrays are useful for hybridization, nucleic acid isolation and purification". One such alternative use of arrays expressly motivated by Pinkel et al. is to use arrays to determine copy number by using comparative fluorescence hybridization. An ordinary practitioner would have been motivated to combine the array of Beattie with the array of Pinkel et al. in order to achieve the expected advantage of developing a sensitive array for enhanced characterization of nucleic acids.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M. Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru

August 23, 2002

JEFFREY SIEW
PRIMARY EXAMINER
8/23/02